SUBJECT: J12-03 – Review of

Proposed "Scope of Work" for

Expert,

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DATE: November 27, 2012

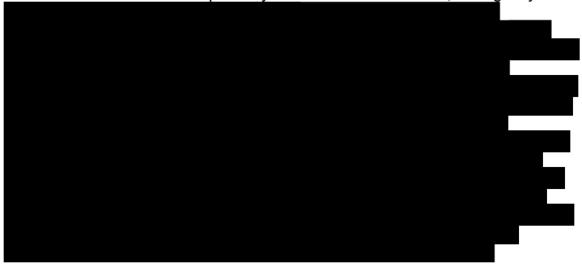
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## An assessment prepared by

if written

according to the directives in the Scope of Work submitted to Audrey Binder for review by EPA will be of limited value to the Agency in evaluation of the potential hazards of the J12-03 submission microorganism, . The directives in that Scope of Work, for the most part, do not address the predominant issue which is the potential for increased incidence of disease if there is increased exposure to the microorganism.

As has been stated repeatedly over the last few months, the Agency





Specific comments on each of the directives follow.

1. Current incidence of compared to other microorganisms known to cause supported by data from research at compared to other supported by data from research or through publications.

This, perhaps, may be useful information if obtained from the scientific literature. However, the data/information, particularly if generated from university laboratory statistics, need to be accompanied by a thorough description of exactly which microorganisms are routinely tested for in exact description of how a designation of a causal agent as would be made.

Statistics from the Michigan State University may not be appropriate for the entire U.S., including its territories, since it well known from the literature that the incidence of its greater in warm, humid climates as opposed to colder ones.

2. Descriptions of other microorganism that are common causes of including examples of microorganisms that thrive in similar conditions

. Please address microorganisms (corrected for spelling errors) on the following list:

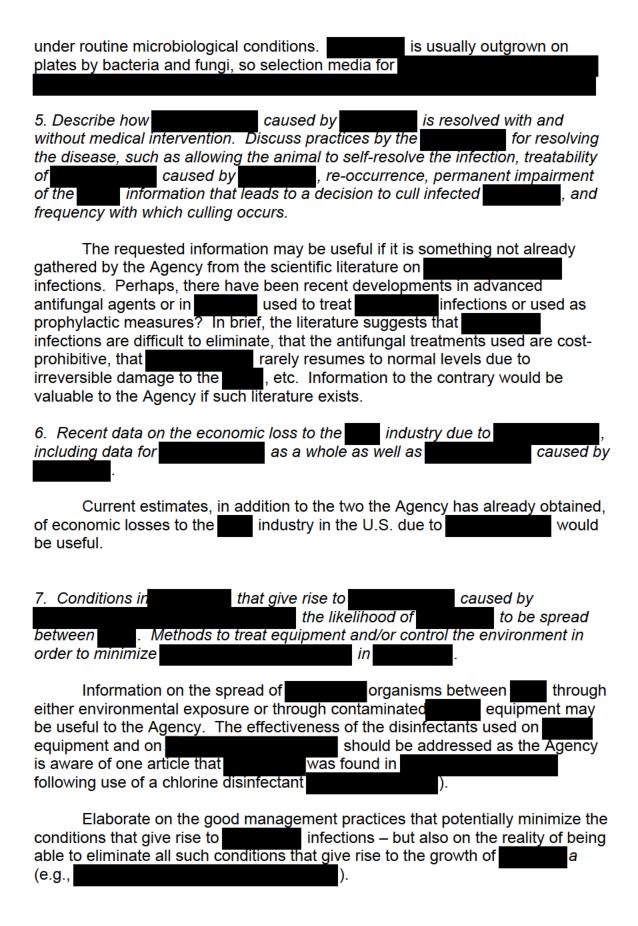
Acetobacter aceti
Saccharomyces cerevisiae
Clostridium acetobutylicum
Escherichia coli K12
Bacillus licheniformis
Aspergillus niger
Aspergillus oryzae
Penicillium roqueforti
Bacillus subtilis

Saccharomyces uvarum (whose currently valid name is *S. bayanus* var. uvarum - from recent phylogenic analyses of the genus which has determined that *S. uvarum* does not warrant separate species status)

The first sentence of this directive may provide useful information and is somewhat a continuation of directive #1.

However, the evaluation of the ten microorganisms listed (which are the 10 eligible recipient microorganisms in our 5(h)4 Exemptions) will be of no use to the Agency as there is no relevance to the issues associated with J12-03. This exercise would be a waste of time and money.

causes of	pecies and subspecies , including a disc . If known, the pe . Specifically a iscussed in trends, in t	ussion of ercentage of address literature	
will be of are but a few articles on numerous articles of	absence of any further rganism for	ncy. The Agency ich the species . Ho identification data omething other th	owever, there are a which indicates that
4. Assess the freque confirmed to be and/or genotype. As caused to identify		c analysis to dete ith which only the	
the response to dire microorganisms are 'negative' for all of the returned with 'negat treat with antibiotics with antifungals next private veterinarian determination of practice – in contrast	and see if the infection t – or even simultaneo called in to further test	seful to know exactications if a samed for. What hap thogens looked for is eliminated? I with both an for the infectious ecies/genotype) ext can be made in	ortly what apple of infected pens if a sample is or? Do then then to the timicrobials? Is a sagent? How does a ver get made in a research laborator.
misidentification of a	view article of	as son , aused by ecause of the po	nething other than stated is probably much tential for



New information on the sources of the pathogenic forms of on and in the environment in general would also be very useful. The Agency is aware of only two articles in which attempts were made to identify the sources of
with and without  ). Articles attempting to find the sources of infection on a or from environmental matrices prior to the concept of the
are of limited value.
8. Describe whether and how management practices in managing caused by have changed in recent decades and whether these changes have decreased or increased incidences of from .
This information would be valuable if available and supported by credible data.
The most valuable question to ask your expert to respond to:
9. Could increased exposure to potentially result in increased incidence of ?